

### REMARKS

Claims 1, 3 and 5-14 were presented for examination in the present application. The instant amendment cancels claims 8, 9 and 14. Thus, claims 1, 3, 5-7 and 10-13 are presented for consideration upon entry of the instant amendment, with is respectfully requested.

Claim 13 was objected to for the misspelling of "2-ethylhexyl acrylate". This informality has been amended as suggested by the Examiner. Applicants respectfully request reconsideration and withdrawal of this rejection.

Independent claim 1, as well as dependent claims 3, 5-12 and 14, were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,254,348 to Hoffman et al. (hereinafter "Hoffman") in view of U.S. Patent No. 5,518,212 to Spada et al. (hereinafter "Spada") and WO 86/06281 to Wick (hereinafter "Wick"). Claims 8, 9 and 14 have been canceled, therefore this rejection is moot.

Claim 1 now provides for a tulobuterol adhesive patch including, inter alia, (a) a support, (b) a pressure-sensitive adhesive layer and (c) a release liner laminated in that order, wherein the pressure-sensitive adhesive layer contains a plasticizer, wherein the amount of the plasticizer is 10-35 wt% of the total weight of the pressure-sensitive adhesive layer, a tulobuterol as a percutaneous absorbing agent, wherein the amount of tulobuterol is 1-10 wt% of the total weight of the pressure-sensitive adhesive layer and the pressure-sensitive adhesive agent is an acrylic-based pressure-sensitive adhesive agent which is a copolymer of an acetoacetoxyalkyl (meth)acrylate and one or more vinyl monomers that are copolymerizable with the acetoacetoxyalkyl (meth)acrylate, wherein the vinyl monomer contains diacetoneacrylamide and/or tetraethyleneglycol dimethacrylate, wherein the amount of acetoacetoxyalkyl (meth)acrylate is 10-45 wt % of the total weight of the acrylic pressure-sensitive adhesive copolymer.

Hoffman provides for a tulobuterol patch for the treatment of bronchial asthma

having a backing layer, an active substance and a matrix layer containing a styrene-butadiene-styrene- or styrene-isoprene-styrene block copolymer. Hoffman fails to disclose or suggest the use of a copolymer of an acetoacetoxyalkyl (meth)acrylate and one or more a vinyl monomers that are copolymerizable with the acetoacetoxyalkyl (meth) acrylate, wherein the vinyl monomer contains diacetoneacrylamide and/or tetraethyleneglycol dimethacrylate, wherein the amount of acetoacetoxyalkyl (meth)acrylate is 10-45 wt % of the total weight of the acrylic pressure-sensitive adhesive copolymer, as recited in claim 1.

Spada provides for a pressure-sensitive adhesive that copolymers of acetoacetoxyalkyl (meth)acrylates and vinyl monomer are used in the pressure sensitive adhesives. Spada fails to teach that the vinyl monomer contains diacetoneacrylamide and/or tetraethyleneglycol dimethacrylate, as recited in claim 1.

Wick provides for an adhesive coated sheet material having a reinforcing monomer such as diacetoneacrylamide.

The tulobuterol adhesive patch as described in Hoffman requires a moderate or proper cohesive strength, since it will be placed on human skin and must be removable. If the patch of Hoffman has an adhesive with a cohesive strength that is too strong it will damage the human skin since the patch must be peeled off with ease after the effective ingredient (i.e., tulobuterol) is released.

To the contrary, in Spada, the copolymers of acetoacetoxyalkyl (meth)acrylates and vinyl monomer are used to increase the cohesive strength of the adhesive (see col. 5, lines 38-43). This feature of the copolymers is important for the end uses of the pressure-sensitive adhesive of Spada (see col. 10, lines 22-37), since a stronger cohesive strength of the pressure-sensitive adhesive is preferred. As a result, the combination of the copolymer of Spada with the tulobuterol adhesive patch of Hoffman destroys the purpose of

Hoffman. Accordingly, one skilled in the art would not have been motivated to combine Spada with Hoffman.

Furthermore, the combination of Wick with Hoffman and Spada does not overcome the deficiencies described above. Thus, the combination as suggested in the Office Action does not provide for the tulobuterol adhesive patch as described in claim 1.

In addition, Spada only teaches that the copolymers of acetoacetoxyalkly (meth)acrylates and vinyl monomer will increase cohesive strength of the adhesive. The inventors of the present application have unexpectedly discovered that the copolymers of acetoacetoxyalkly (meth)acrylates and vinyl monomer have very high compatibility with tulobuterol and a lipophilic oil plasticizer. As a result, the tulobuterol adhesive patch comprising the copolymers of acetoacetoxyalkly (meth)acrylates and vinyl monomer containing diacetoneacrylamide and/or tetraethyleneglycol provide improved release of tulobuterol, improved skin permeability and a reduction in skin irritation, all of which are entirely unexpected (see Paragraphs [0005] and [0006] of the present application).

In particular, the specific amounts recited in claim 1 make the improved effects of the present application more advantageous: the plasticizer, 10-35 wt% of the total weight of the pressure-sensitive adhesive layer, the tulobuterol, 1-10 wt% of the total weight of the pressure-sensitive adhesive layer, and the acetoacetoxyalkly (meth)acrylate, 10-45 wt% of the total weight of the total weight of the acrylic pressure-sensitive adhesive copolymer.

As explained above, the function of the copolymer described in Spada and the present application is completely different. Accordingly, one skilled in the art would not have predicted the results received with the combination of plasticizer, the tulobuterol and the acetoacetoxyalkly (meth)acrylate, provided in

claim 1 of the present application. Accordingly, it would not have been obvious to one skilled in the art to combine Hoffman with Spada and Wick.

Therefore, for at least the reasons described above and those provided for independent claim 1, dependent claims 3, 5-7 and 10-12 are patentable over Hoffman and Spada alone or in combination with Wick. Thus, dependent claims 3, 5-7 and 10-12 are in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 3, 5-7 and 10-12.

Dependent claim 13 is rejected under 35 U.S.C. §103(a) as being unpatentable over Hoffman, Spada and Wick as applied to claims 1, 3, 5-12 and 14, and further in view of U.S. Patent No. 6,632,906 to Kamiyama (hereinafter "Kamiyama"). Applicants respectfully traverse this rejection for the reasons below.

Hoffman, Spada and Wick are described above. Kamiyama was cited as teaching that 2-ethylhexyl acrylate, methyl methacrylate, butyl acrylate, diacetone acrylamide and tetraethyleneglycol dimethacrylate may be used to form the adhesion. The addition of the adhesives provided in Kamiyama to the patch of Hoffman, Spada and Wick do not overcome the deficiencies as described above for claim 1, or provide for the unexpected results received in the present application. Thus, the combination as suggested in the Office Action does not provide for the tulobuterol adhesive patch as described claim 1.

Accordingly, for at least the reasons described above and those provided for independent claim 1, dependent claim 13 is patentable over Hoffman, Spada and Wick alone or in combination with Kamiyama. Therefore, dependent claim 13 is in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 13.

In view of the foregoing, Applicants respectfully submit that all claims present in this application patentably distinguish over the cited prior art and cited combinations of

the same. Accordingly, Applicants respectfully request favorable reconsideration and withdrawal of the rejections of the claims. Also, Applicants respectfully request that this application be passed to allowance.

If for any reason the Examiner feels that consultation with Applicants' attorney would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

Respectfully submitted,

June 1, 2010



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